UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,394	10/19/2005	Zairen Sun	ORIGEN-0015 A	3492

23599 7590 09/20/2007

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,394	SUN ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10/19/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-26 are pending in the application and are currently under prosecution.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group 1, claims 1-4, all in-part are drawn to an isolated polynucleotide which codes for SEQ ID NO:2

Groups 2-34, claims 1-4, 8-9 all in-part wherein each group is drawn one of the polynucleotide sequences which code without interruption for an amino acid sequences selected from the group of SEQ ID NOS, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100 and a method of detecting said polynucleotide.

Groups 35-68, claims 5-7 all in-part wherein each group is drawn to one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 69-101, Claims 8-9, all-in-part, wherein each group is drawn to a method of detecting a nucleic acid encoding one of the amino acid selected from the group of SEQ ID NOS 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 102-135, Claims 10-11, both-in-part wherein each group is drawn to a method of treating cancer showing altered expression of a differentially regulated human cancer gene with an effective agent, wherein the effective agent is an antibody.

Groups 136-169, Claims 10-11, both-in-part wherein each group is drawn to a method of treating cancer showing altered expression of a differentially regulated human cancer gene with an effective agent, wherein the effective agent is an antisense.

Groups 170-203, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing a cancer associated with abnormal expression of a

differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is measuring expression level of mRNA.

Groups 204-237, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is determining the genomic structure of the gene.

Groups 238-271, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is determining the mRNA structure of transcripts from said gene.

Groups 272-301, Claims 12-13, all-in-part wherein each group is drawn to a method of diagnosing a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is measuring expression level of polypeptide coded for by said gene.

Groups 302-335, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing susceptibility to a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is measuring expression level of mRNA.

Groups 336-369, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing susceptibility to a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is determining the genomic structure of the gene.

Groups 370-403, Claims 12-14, all-in-part wherein each group is drawn to a method of diagnosing susceptibility to a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the expression, wherein the assessing is determining the mRNA structure of transcripts from said gene.

Groups 404-437, Claims 12-13, all-in-part wherein each group is drawn to a method of diagnosing susceptibility to a cancer associated with abnormal expression of a differentially regulated cancer gene, comprising assessing the

expression, wherein the assessing is measuring expression level of polypeptide coded for by said gene.

Groups 438, Claim 15-in-part wherein each group is drawn to a method of assessing a therapeutic intervention in a subject comprising determining the protein expression level, as contemplated in the specification, of the genes set forth in Claim 1.

Groups 439, Claim 15-in-part wherein each group is drawn to a method of assessing a therapeutic intervention in a subject comprising determining the mRNA expression level, as contemplated in the specification, of the genes set forth in Claim 1.

Groups 440, Claim 15-in-part wherein each group is drawn to a method of assessing a preventive intervention in a subject comprising determining the protein expression level, as contemplated in the specification, of the genes set forth in Claim 1.

Groups 441, Claim 15-in-part wherein each group is drawn to a method of assessing a preventive intervention in a subject comprising determining the mRNA expression level, as contemplated in the specification, of the genes set forth in Claim 1.

Groups 442-476, Claim 16-in-part wherein each group is drawn to a method of identifying an agent that that modulates the expression of mRNA expressed by a differentially expressed cancer gene that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 477-510, Claims 16-18, all-in-part wherein each group is drawn to a method of identifying an agent that that modulates the expression of protein expressed by a differentially expressed cancer gene that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 511-544, Claim 19-in-part wherein each group is drawn to a method of detecting a polymorphism in genomic DNA of differentially regulated cancer

genes that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 545-578, Claim 19-in-part wherein each group is drawn to a method of detecting a polymorphism in mRNA of differentially regulated cancer genes that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 579-612, Claim 19-in-part wherein each group is drawn to a method of detecting a polymorphism in polypeptide encoded by differentially regulated cancer genes that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Groups 613-646, Claims 20-21, both-in-part wherein each group is drawn to a method of identifying a genetic basis for prostate or breast cancer comprising determining the association of polypeptide that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100 with cancer wherein the determining is performed by producing a human-linkage map using said polynucleotide.

Groups 647-680, Claims 20 and 22, both-in-part wherein each group is drawn to a method of identifying a genetic basis for prostate or breast cancer comprising determining the association of polypeptide that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100 with cancer wherein the determining is performed by comparing the nucleotide sequences of said polynucleotide between normal subjects and subjects having cancer.

Groups 681-714, Claim 23-in-part wherein each group is drawn to a transgenic non-human mammal whose genome comprises a functional disruption of a homolog of a differentially regulated cancer gene that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96,

100 with cancer wherein the determining is performed by producing a human-linkage map using said polynucleotide.

Groups 715-768, Claim 23-in-part wherein each group is drawn to a cell from a transgenic non-human mammal whose genome comprises a functional disruption of a homolog of a differentially regulated cancer gene that encodes one of the amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100 with cancer wherein the determining is performed by producing a human-linkage map using said polynucleotide.

Groups 768-812, Claim 24-in-part wherein each group is drawn to an antibody that is specific for an amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Group 813, Claim 25-in-part is drawn to a method of advertising differentially regulated cancer genes for sale, commercial use or licensing comprising displaying in a computer-readable medium a polynucleotide that encodes an amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

Group 814, Claim 26-in-part is drawn to a method of selecting from a database, a polynucleotide sequence that encodes an amino acid selected from the group of SEQ ID NOS, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 46, 51, 49, 53, 55, 57, 559, 61, 63, 65, 67, 69, 71, 73, 75, 87, 89, 96, 100.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the

manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, forms a single general inventive concept comprising a polynucleotide and a method of detecting said polynucleotide.

Groups 2-814 are products different from that of Group 1 and methods clearly different from that of Group 1 Given that the claims are all drawn to methods different from Group 1 and products different from that of Group 1, the additional claimed methods do not meet the requirement for categories considered to have unity of invention.

For these reasons the claimed inventions are not so linked as to form a single general inventive concept and all methods are properly broken out as separate groups.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898.. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
September 7, 2007